

AWARD NUMBER: W81XWH-15-1-0712

TITLE: Smart Adaptive Socket to Improve Fit and Relieve Pain in Wounded Warriors

PRINCIPAL INVESTIGATOR: Dr. David Boone

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Edmonds, WA 98020

REPORT DATE: October 2016

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Fort Detrick, Maryland 21702-5012

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14. ABSTRACT Enter a brief (approximately 200 words) unclassified summary of the most significant finding during the research period. A silent and compact vacuum pump was developed and tested. A prototype liner with viscoelastic adaptive volume elements was also developed and tested. Computer, Android, and iPhone applications were developed for wireless interaction with the socket system firmware. A control algorithm was designed and tested. Clinical trial protocol was developed and submitted for approval.					
15. SUBJECT TERMS Volume compensation, Viscoelastic, Vacuum pump, Liner, Prosthetic socket interface, Dynamic segmental volume control, Wireless connection, Pressure control system.					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
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Unclassified	Unclassified	Unclassified	Unclassified	21	

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INTRODUCTION:

A prosthetic socket is the physical connection between the user's body and the prosthesis. The functionality and comfort of the prosthesis is to a great degree determined by the intimacy of this connection. Fluctuations in body volume lead to changes in socket fit that negatively influence limb health. These volume changes can be due to the long-term effects of pharmaceuticals, weight gain, or weight loss. Limb volume can also decrease quite noticeably (as much as 11%) throughout the day due to the venous return of fluid out of the tissue caused by the forces of ambulation. This project directly addresses the prevalent and unmet need of prosthetic users for a socket that accommodates a changing residual limb volume while maintaining comfort and fit. We will develop and complete preliminary real world human wear test validation for a smart adaptive socket system (SASS) that controls limb loading and socket fit through dynamic segmental volume control. The system includes a liner with three distinct viscoelastic foam volume elements and a silent relatively mild vacuum suspension system, which is also used to control the volume in the liner by evacuating and compressing the foam elements. This system provides improved stability, proprioception, and reduced abrasion by eliminating voids and excess pressure in the socket.

KEYWORDS: *Provide a brief list of keywords (limit to 20 words).*

SASS – *Smart Adaptive Socket System including a liner and a vacuum pump.*

Volume Element – *A viscoelastic foam element that built into the liner that can be expanded or compressed to compensate for volume changes in the limb.*

Viscoelastic Foam – *Foam that has both viscous and elastic properties, which vary with strain, strain rate, and frequency.*

DMA – *Dynamic Mechanical Analysis – A type of testing machine commonly used to find the glass transition temperature, which can also be used to do dynamic compression tests at controlled temperatures. It is 10 to 100 times more sensitive than DSC or DTA to changes occurring at the glass transition temperature.*

Bending Plateau – *The second of the three regions of compression of viscoelastic foam where the cell walls are bending and the elastic modulus is relatively constant.*

ACCOMPLISHMENTS: .

What were the major goals of the project?

Aim 1: Design SASS Systems

1.1 Optimal adaptive element layout

1.2 Refine material selection

1.2.a Optimize for: thermal dependence

1.2.b Maximum patient comfort

1.2.c improve response times for changes in volume

1.2.d Maximize range of compression region 2 the elastic buckling plateau

1 3 Refine and implement adaptive control algorithm

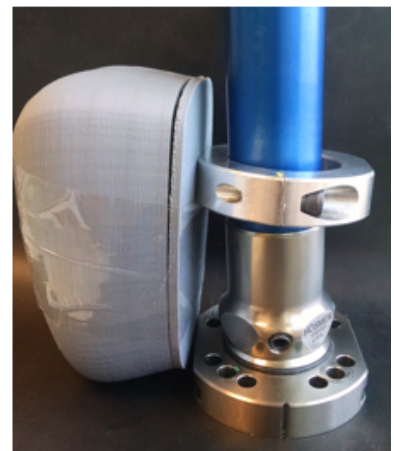
- 1.3.a Large posterior element maintains a even mean pressure (snugness)
- 1.3.b stabilizing element to reduce coronal plane moments
- 1.3.c Distal element: Maintain tolerable contact - indicate insufficient support of other 2 elements
- 1.3.d Manual mode
- 1.3.e On board pressure transducer for each element
- 1.3.f Smart Pyr sensor
- 1.3.g 'Sport' vs 'Comfort' mode

Aim 2: Clinical feedback development trial

- 2.1 Recruit 15 individuals with war-related limb loss
- 2.2 Build prototype liners with 3 VE elements with discrete volume control
- 2.3 Long term use testing

What was accomplished under these goals?

1. Major Activities: A volume element material was chosen and tested for the desired properties. A vacuum pump was developed and bench tested. A control algorithm was developed and implemented for the vacuum pump. A user interface was developed for computers, androids, and iphones.
2. Specific Objectives: Aim 1: Finalized mechanical and electrical design of the pump and the initial mechanical design of the pump liner connection. The creation of the pump. Aim 1.1: Developing a liner fabrication method and finalizing the foam element layout through the creation of prototype liners. Aim 1.2: A volume element material was developed and the important properties of the viscoelastic foam were characterized. Aim 1.3: An adaptive control algorithm was developed, implemented, and tested for the vacuum pump and an algorithm was designed for volume element control. Aim 2: A protocol for clinical trials was developed.
3. Results:
 - 3.1 Overview:
 - a. *Vacuum Pump Design and Testing*: The mechanical and electrical design of the pump was iteratively redesigned and a final compact, quiet, affordable version of the pump was manufactured. Lifetime, evacuation rate, and environmental tests were conducted.
 - b. *Materials Selection and Characterization*: Utilizing the consulting services of Bergad Specialty Foams viscoelastic polyurethane foam was fabricated with the required properties for the liner volume elements. The relevant material properties were characterized.
 - c. *Liner Design and Fabrication*: Volume element placement was finalized and a manufacturing method was developed. An interface was designed between the liner and the vacuum pump.
 - d. *Adaptive Control Algorithm Design and Testing*: An adaptive control algorithm was developed for the pump and implemented in the firmware. The control algorithm was further refined during testing. Software applications for computer and mobile devices were developed to display live pressure data, test the control algorithm, and allow patient control.
 - 3.2 Discussion of Results:
 - a. *Vacuum Pump Design and Testing*:



Starting with the test bed and the rapid prototyped shell shown in figure 1 the pump was iteratively redesigned with an emphasis on decreasing the operating noise, volume, and cost. The durrability and manufacturing process were also improved.

$$19.2 \text{ in}^3$$

16.2 in³ (\$418)

16.2 in³ (\$370)

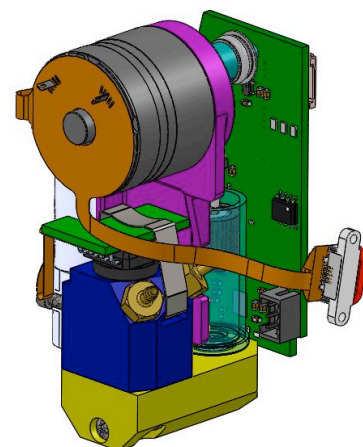
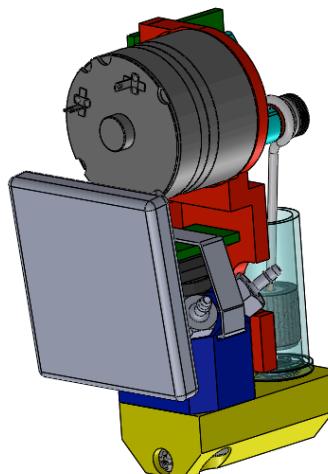
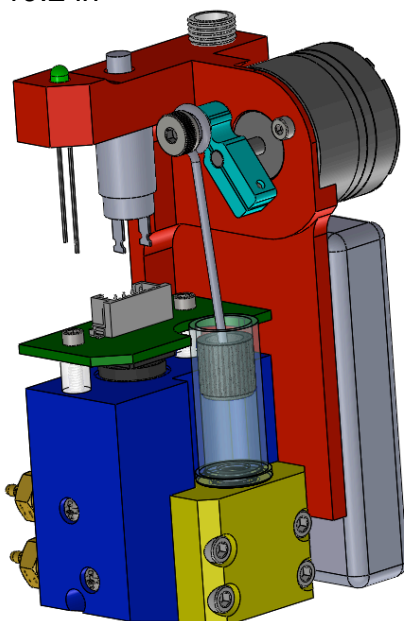


Figure 2 - Three iterations of the vacuum pump design. Showing, from left to right, the decrease in size and cost and the features added to improve reliability.

Three prototype pumps with the structures shown in figure 2 were built and tested. The pump design was finalized and the pump shown in figure 3 was built.

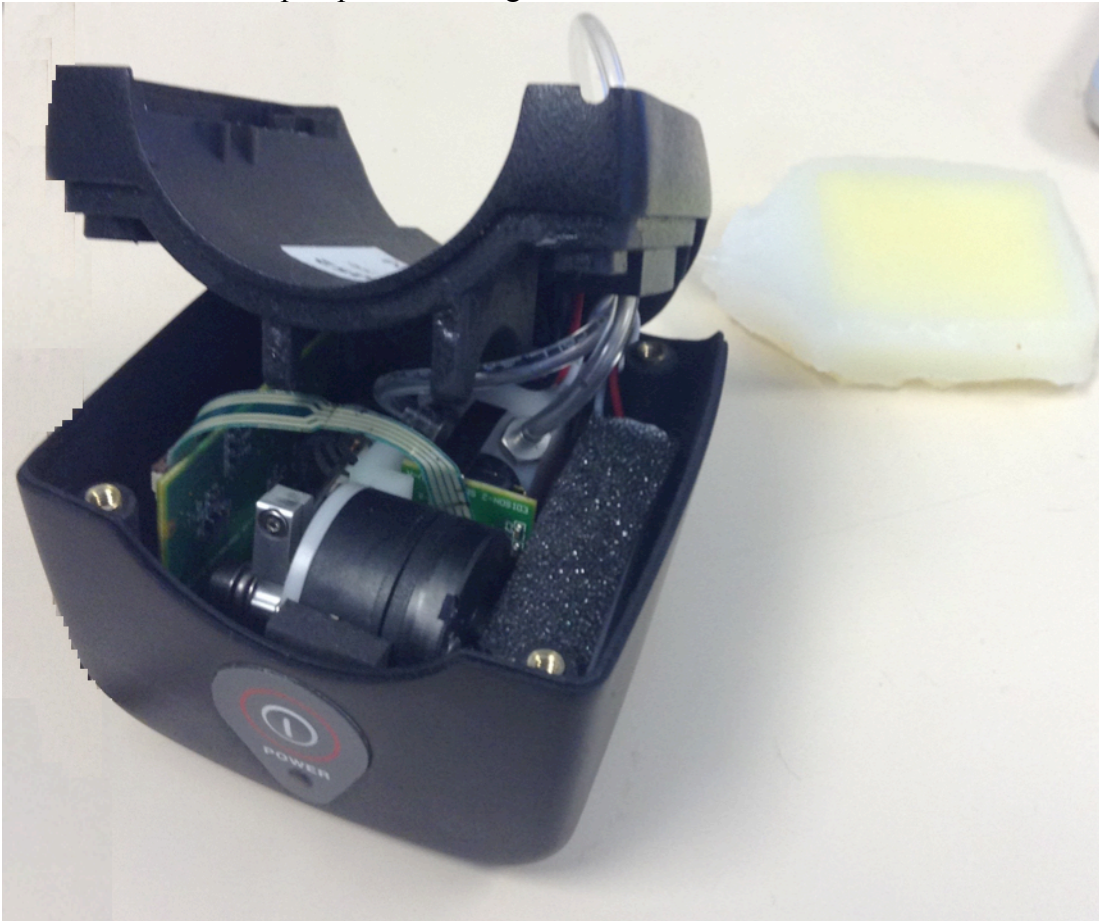


Figure 3 - The current vacuum pump design open so that the internal components are visible.

Lifetime tests were conducted for three years of pump cycles and the evacuation rate of the pump was tested after each equivalent year. The evacuation rates remained constant and no visible damage was detected. The pump was also tested for the effect of water damage.

Table 1 - The evacuation rates for the vacuum pump after one, two, and three year equivalents of pump cycles.

	BaseLine	Year 1	Year 2	Year 3
Low-Med Pump Cycles	0	880110	1612403	2326288
Med-High Pump Cycles	0	706021	986433	1418669
Time to 5 inHg(s)	4	4.3	4	4
Time to 10 inHg(s)	11.3	10.7	10.7	10.7
Time to 15 inHg(s)	26.7	23.7	23.3	24.3
Time to 17 inHg(s)	40.7	35.3	34	34.7

b. *Materials Selection and Characterization:*

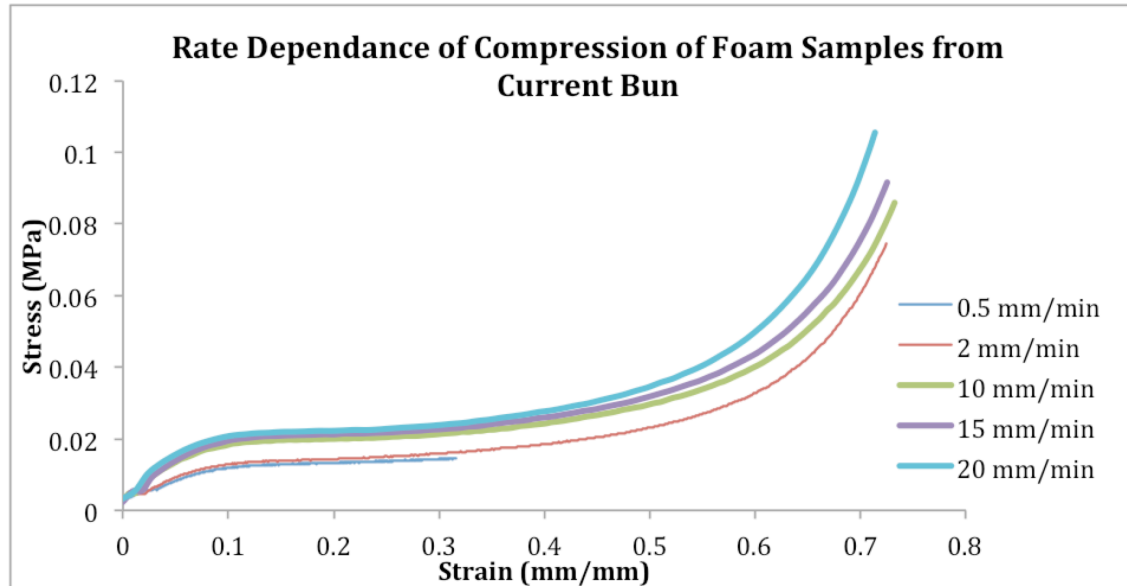


Figure 4 - Rate dependence of foam compression tests

Viscoelastic open celled polyurethane foam was developed for the liner volume elements. The foam was formulated to achieve the desired firmness, density, return time, and sufficient air permeability. Important material properties of the final foam choice were then characterized. Compression tests were conducted at varying rates of compression. A slow nearly static rate of compression was used to determine the bending plateau. The range of the bending plateau dictates the functional range of the foam because it is an area of elastic deformation with a relatively small and constant elastic modulus. This means that in this range the volume of the foam can be changed without causing any permanent deformation or varying how firm it feels against the leg.

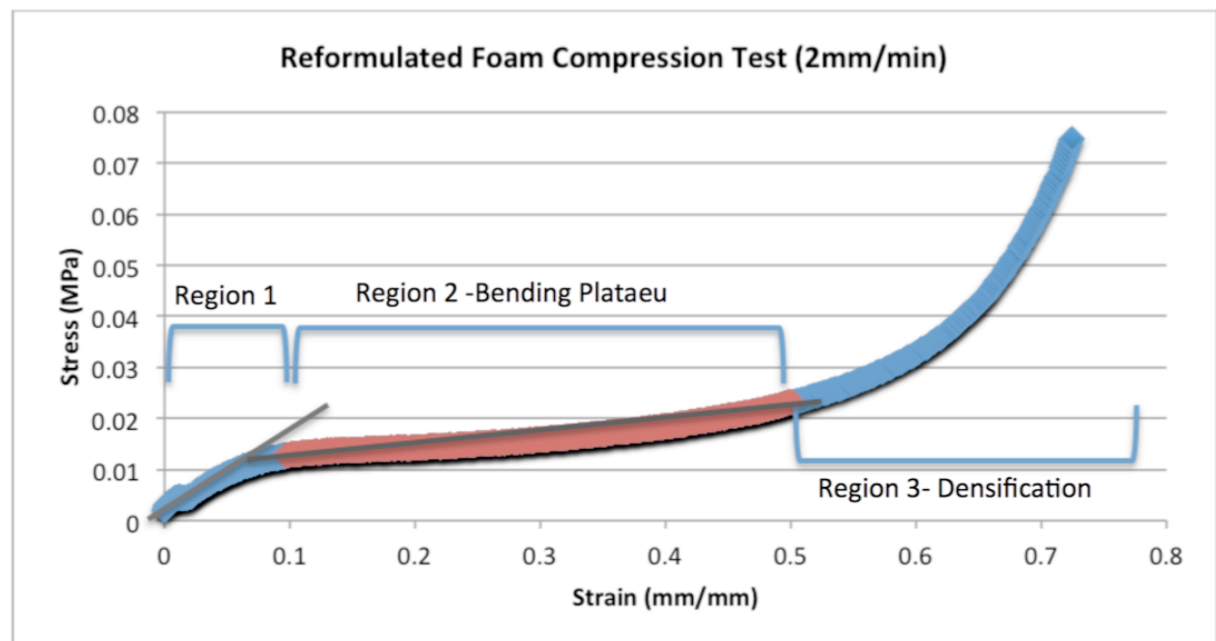


Figure 5 - Compression curve for the viscoelastic foam with the second region of compression highlighted.

The decompression time was also measured. The force caused by the pressure of the foam expanding between the plates was at a minimum for a brief period while the foam returned to its original thickness (figure 5). This time, the initial relaxation time shown on the right, was on average about 1s. After 5 seconds the foam had returned to within 3% of its initial firmness. This is shown as the total relaxation time on the left. It took an average time of about 10 minutes for the foam to completely return to its original stiffness. This means that the foam will feel firm for compressions on the order of 1 Hz such as walking and it will take 5-10 minutes to fully adjust to changing the settings.

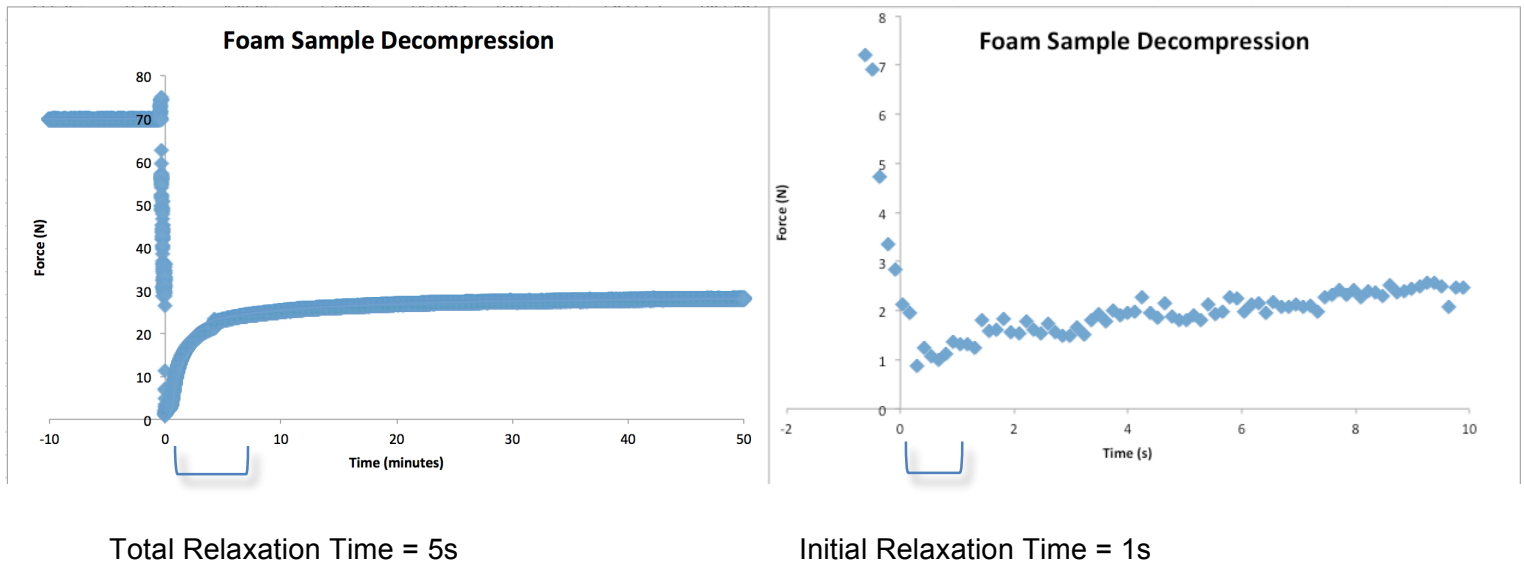


Figure 6 - Force of the decompressing foam on parallel plates a fixed distance apart.

The melt and transition temperatures were determined using a dynamic mechanical analyzer (DMA) temperature scan ranging from -50 to 300 °C. The sample was repeatedly compressed at a constant frequency and with a static and dynamic force. As the temperature was steadily increased, changes in the amount of deflection were measured.

The glass transition temperature indicated by the drop in the storage modulus curve was about 12.4 °C. However, the peaks of the loss modulus and tangent delta curves, give glass transition temperatures of 16 °C and 27.3 °C respectively. The foam is not a simple homogenous material so the transition occurs over a spread of temperatures, which is referred to as the transition region

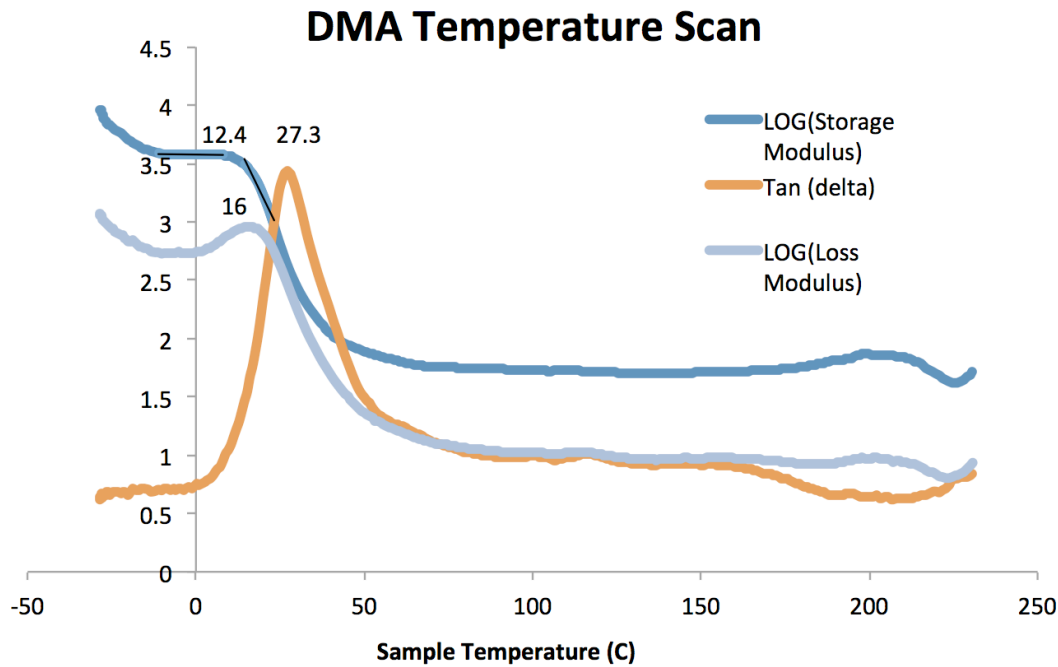


Figure 7 - DMA scan results showing three values for the glass transition temperature.

Airflow, measured according to ASTM standard D3574-11, was found to be 1394 mm²/s. This is significantly greater than the required airflow of 5 mm²/s which was calculated from the foam density, the probable volume, and the expected rate of evacuation. The airflow will not limit the compression rate of the foam elements.

Static fatigue resistance was also measured according to ASTM standard D3574-11. A sample of foam was statically compressed and held for 24 hours at 50% compression. The thickness of the sample was measured before and after compression. The average change in thickness, measured 30 minutes after static compression was released, was 3.4%, which is less than the uncertainty of the measurement. This signifies that the foam is resilient to static fatigue.

Table 2 shows a summary of the material properties for the chosen viscoelastic foam. It includes required values for the elastic modulus and the bending plateau range, which were determined to allow for sufficient support and volume accommodation.

Table 2 - Material properties and their target values for the volume element foam.

	Reformulated 6206c	Required Values	Related Property	Test
Elastic Modulus (@0.5 mm/min)	1.1076 MPa	> .0659 MPa	Firmness	Compression
Bending Plateau Range	10%-50%	> 30%	Firmness	Compression
Relaxation Time (t1)	0.746 ± .09 s	≥ 1s	Viscosity	Decompression Tests
Relaxation Time (t2)	10 minutes	≥ 10s	Viscosity	DMA/Decompression
%Thickness Lost	0%	< 10%	Durability	Static Fatigue Test
Glass Transition Temperature	12.4 C	10C	Temp	DMA
IFD	600 N	> 200N	Firmness	IFD Machine
Density	1.0825x10 ⁻⁵ g/cm ³	> .56x 10 ⁻⁵ g/cm ³	Density	Scale and Ruler
Air Permeability	0.9 ft ³ /min	> .002857 ft ³ /min	Air Permeability	Air Permeability
Onset of Densification	50% Compression		Ductility	Instron
Max Linear Elastic Stress	.01081 MPa		Elasticity/Firmness	Instron
Melting Point	226.76C	> 57 C	Temp Range	DMA

c. *Liner Design and Fabrication:*

Different designs and fabrication methods were investigated for the liner. It was found that an even distribution of foam around the liner was too difficult to roll during donning and we expect that an even foam distribution would not produce an optimal pressure distribution in the socket. Two designs with a posterior element and two medial elements located at either side of the tibia were also created and tested. In the first design separate foam elements with thicknesses of 15mm were used. However, it was found that the 15mm thickness was difficult to handle and because of their thickness the elements created uneven areas of pressure. The next prototype included three connected elements with a thickness of 5mm. This improved the handling but did not allow for sufficient volume change.

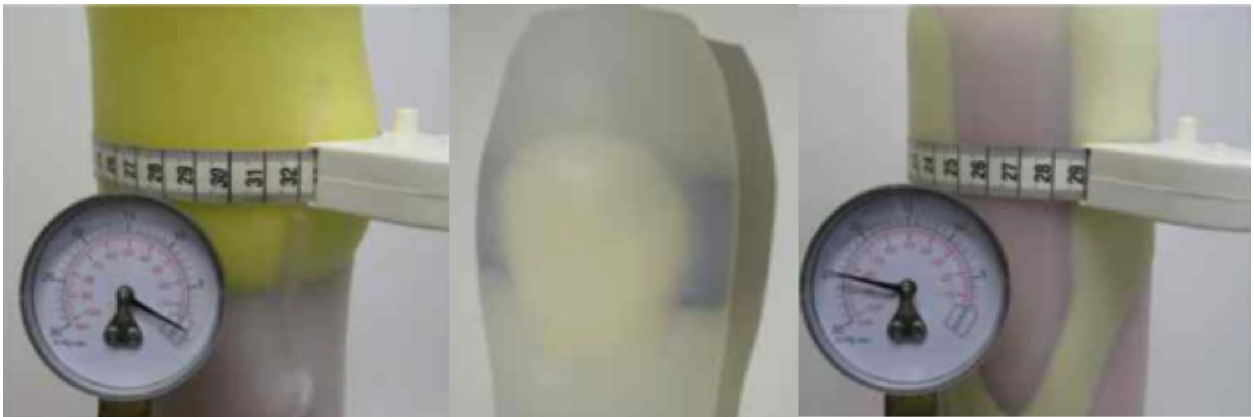


Figure 8 - Prototype liners investigating different volume element layouts and thicknesses.

The current design utilizes three volume elements to support secure and balance the limb. An average thickness of 8mm allows for a volume change comparable to a 5-ply sock, which is sufficient to accommodate daily volume fluctuations. The handling of the liner was also improved by adding diagonal slices to some of the volume elements, to create additional flexibility.

Silicon was chosen for the liner material because of its low creep, hardness, thermal conductivity, and compatibility with a socket environment. Silicones and urethanes are harder than thermoplastic elastomers with durometers between 00-35 and 00-50. Skin has a durometer of 00-70 and the best comfort is achieved by using a liner material that is close to, but slightly softer than, the hardness of the skin it will be in contact with.

With the collaboration of a consulting prosthetist, three liner fabrication methods were investigated. Injection molding required that the volume elements be pre-encased in silicon and compressed before being placed in the mold. The mold could then be filled with liquid silicon. Another method investigated was using a thickening agent to make the silicone viscous enough to paint onto the limb mold. The volume elements were placed on the initial layer then more viscous silicone was used to cover them and complete the liner. It was decided that layering the volume elements between

premade thin silicone liners bonded with liquid silicone was the preferred manufacturing method. A prototype liner was manufactured using this method. Silicon tubes were used to connect the volume elements to each other and to the vacuum pump.



Figure 9 - Prototype liners investigating different manufacturing methods. Painted viscous silicon (left) and layering thin premade liners (right)

A design for the liner pump interface through the prosthetic socket was also developed. The design involves a quick disconnect connection between the posterior and medial volume elements and the vacuum pump in the base of the socket. It also includes a slow leak check valve between the distal volume element and the atmosphere, which allows the quick expulsion of air on a step and the subsequent slow expansion of the element.

d. *Adaptive Control Algorithm Design and Testing:*

An adaptive control algorithm for controlling the vacuum level and step detection functions of the pump was developed and refined. Software applications for mobile devices and computers were also developed to allow for user control and to assist with testing and improving the control algorithm by displaying the actual and target vacuum levels and step detection in real time. The basic structure of the control algorithm is as follows. On startup a session is initiated. The device enters donning mode and attempts to reach the target donning pressure by operating either the valve or the pump. If the pressure stabilizes at the target donning pressure the device moves into run

mode. However, if a timeout is reached before the pressure stabilizes donning fails and the device must be reset. This allows the patient to readjust the socket seal and restart the donning process. In run mode, the device transitions between three activity levels. Each activity level is defined by a step rate and has an associated target vacuum level. Both the step rate and target vacuum are adjustable variables, which can be used to fit the device to a patient. For example, a patient with a quick normal walking speed could have a higher step rate associated with the medium activity level than someone with a slow normal walking speed. A patient with a particularly heavy prosthesis could have a higher target vacuum level.

The pressure sensor in the device is connected to the socket port and measures raw air pressure data at a sample rate of 50 Hz. A filter is then used to smooth the raw data. During run mode, filtered pressure data is used to determine when valve and pump operations are necessary to maintain the target vacuum level. Pressure data is also used to detect steps and determine which activity mode the device should be in. If the pressure fluctuations caused by a step are too large it signifies that the limb is too loose in the socket and the volume elements are adjusted to compensate. Diagrams detailing the control algorithm are included in the appendix.

Three secure bonding modes were added to the firmware to ensure that only authorized devices are allowed to communicate with the unit. This protects the patient's data and ensures their safety. Unique bonding codes for devices used by the patient and prosthetist are stored in the firmware and checked when a new connection is made. There is also a terminal bonding mode for the initial device setup.

Computer interface software was developed for performing firmware tests and debugging the control algorithm.

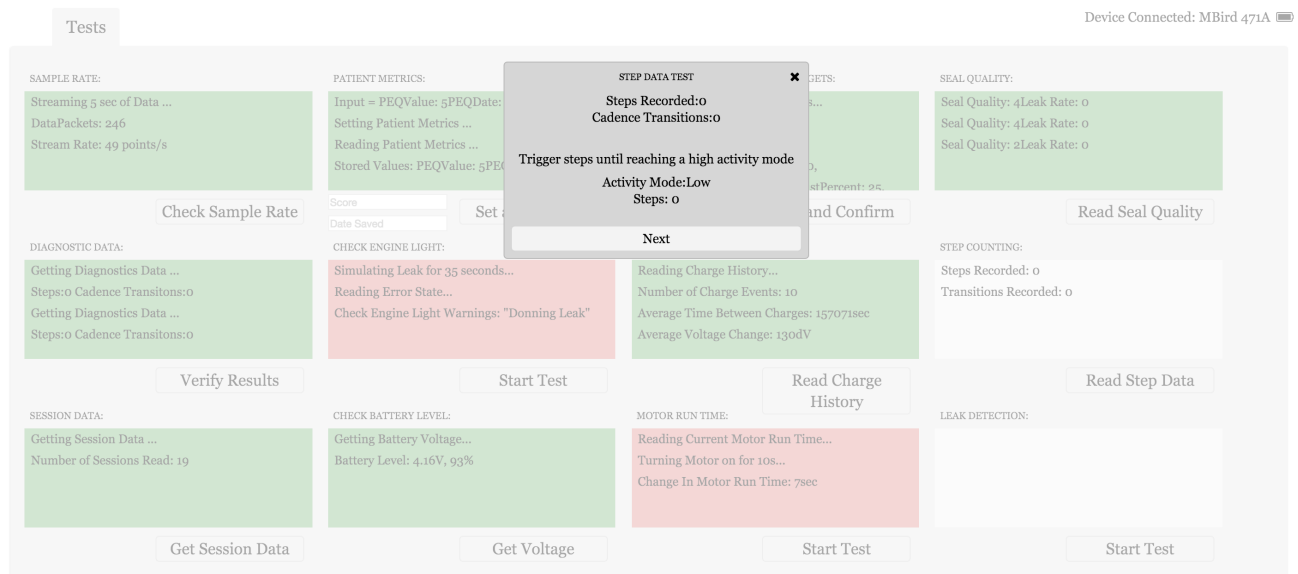


Figure 10 - Computer software interface in the middle of a step detection test.

Mobile software was also developed for apple and android devices. This software will allow users and prosthetists to interact with the liner pump system and adjust settings. The software also provides a realtime graph of the current pressure in the socket.

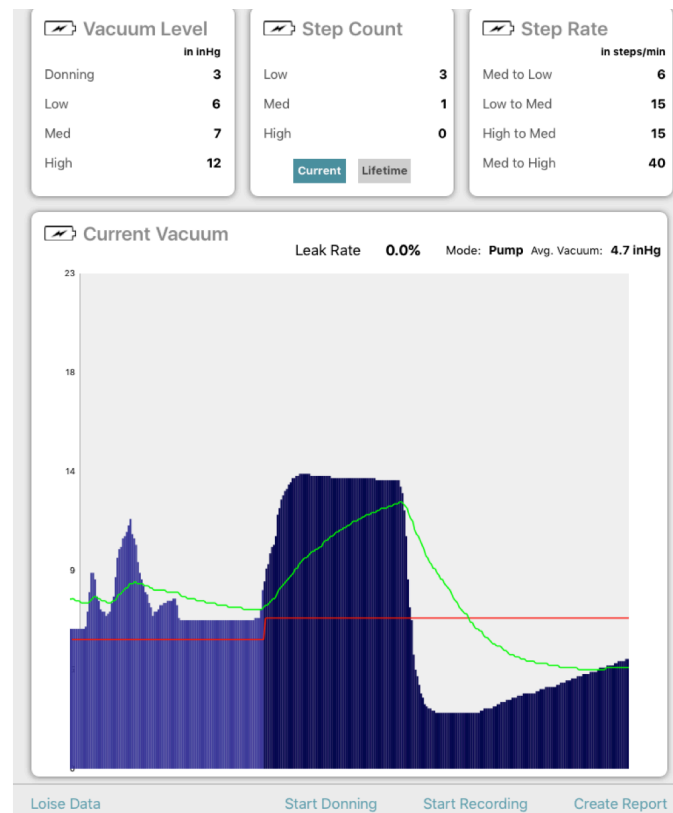


Figure 11 - Mobile software showing the socket pressure, the target pressure, the mode and the pump settings in real time.

What opportunities for training and professional development has the project provided?

Nothing to Report.

How were the results disseminated to communities of interest?

Nothing to Report

What do you plan to do during the next reporting period to accomplish the goals?

A new liner incorporating the quick disconnect interface with the pump will be fabricated. The control algorithm for the volume elements will be refined and tested. Clinical trials will be arranged and work will begin on the fabrication of liner systems for use in the clinical trials.

4. **IMPACT:**

What was the impact on the development of the principal discipline(s) of the project?

Nothing to Report

What was the impact on other disciplines?

Nothing to Report

What was the impact on technology transfer?

Nothing to Report

What was the impact on society beyond science and technology?

The project will improve living conditions for transtibial amputees.

5. **CHANGES/PROBLEMS:**

Changes in approach and reasons for change

Nothing to Report

Actual or anticipated problems or delays and actions or plans to resolve them

There may be delays in the approval process for the clinical trials. We are planning to work with two VA hospitals in Florida which both have their own internal review boards. However the approval process has already been started. There are no other anticipated delays.

Changes that had a significant impact on expenditures

Nothing to Report

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Nothing to Report

6. **PRODUCTS:**

Nothing to Report

7. **PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS**

What individuals have worked on the project?

Name:	David Boone, PhD
Project Role:	Principal Investigator
Research Identifier:	0000-0002-9479-8396
Nearest person month worked:	4
Contribution to Project:	No Change

Name:	Lucas Lincoln
Project Role:	Technical Supervisor
Research Identifier:	0000-0002-7139-0267
Nearest person month worked:	1
Contribution to Project:	No Change

Name:	Aaron Griswold
Project Role:	Project manager
Research Identifier:	0000-0002-5154-2315
Nearest person month worked:	3
Contribution to Project:	No Change

Name:	Courtney Fisher
Project Role:	Mechanical Engineer
Research Identifier:	0000-0003-4315-3835
Nearest person month worked:	5
Contribution to Project:	No Change

Name:	Ray Austin
Project Role:	Electrical Engineer
Research Identifier:	0000-0002-0586-9966
Nearest person month worked:	3
Contribution to Project:	No Change

Name:	Jonathan Maier
Project Role:	Software/Firmware
Research Identifier:	0000-0002-2885-6622

Nearest person month worked: 4
 Contribution to Project: No Change

Name: Aizen Ulric
 Project Role: Materials Engineer
 Research Identifier: 0000-0002-8133-4541
 Nearest person month worked: 3
 Contribution to Project: No Change

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

Nothing to Report

What other organizations were involved as partners?

Organization Name: Cadence Biomedical

Location of Organization: Seattle, WA

Partner's contribution to the project (*identify one or more*)

Collaboration Staff exchanged knowledge and tools for liner manufacturing.

8. SPECIAL REPORTING REQUIREMENTS

QUAD CHARTS:

Smart Adaptive Socket for lower extremity prosthetic users

Log Number: OR140328

Award Number: W81XWH-15-1-0712

PI: Boone, David

Org: Orthocare Innovations

Award Amount: \$747,345

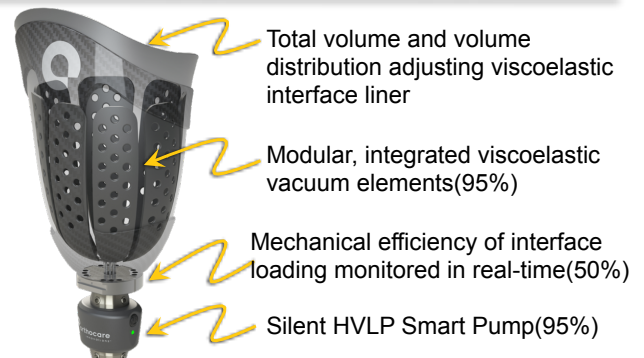


Product Development Aims

- Refine viscoelastic interface liner for manufacturability
- Optimize and validate hardware
- Validate control algorithm integrating force data for optimal fit
- Determine number of elements with user feedback
- Develop smart phone App to enable user control of parameters

Approach

We propose to develop a Smart Adaptive Socket that will dynamically adapt contact pressure on the residual limb to ensure a superior fit with high performance when needed, and will modulate pressure for periods of comfort during rest. The pressure within 8 viscoelastic vacuum elements will be modulated using a silent pump with force and pressure sensing input and a dynamic control algorithm. User control with smart phone App.



We have developed a silent, high volume low pressure (HVLP) pump to modulate interface shape. We have developed, marketed and published 9 peer-reviewed publications validating our load sensing element

Timeline and Cost

Activities	CY	15	16	17
Refine Viscoelastic Interface				
Define vacuum element locations				
Validate Hardware software and controls				
User testing of Smart Adaptive Socket				
Estimated Budget (\$K)		\$94	\$374	\$279

Updated: 9/30/16

Goals/Milestones (Example)

CY15 Goal – Complete system specifications

- ☑ Refine material engineering of interface
- ☑ Bench test functionality
- ☑ Initiate prototyping of smart pump and control system

CY16 Goals – Systems Integration

- ☑ Design and Produce prototype adaptive viscoelastic liners
- ☑ Design and Produce prototype smart pump control system

CY17 Goal – Patient testing

- ☐ Field test on amputee subjects

Comments/Challenges/Issues/Concerns

- To enhance future manufacturability of the technology we engaged the help of an existing prosthetic liner manufacturer for fabrication of prototypes.

Budget Expenditure to Date

Projected Expenditure: \$360,594

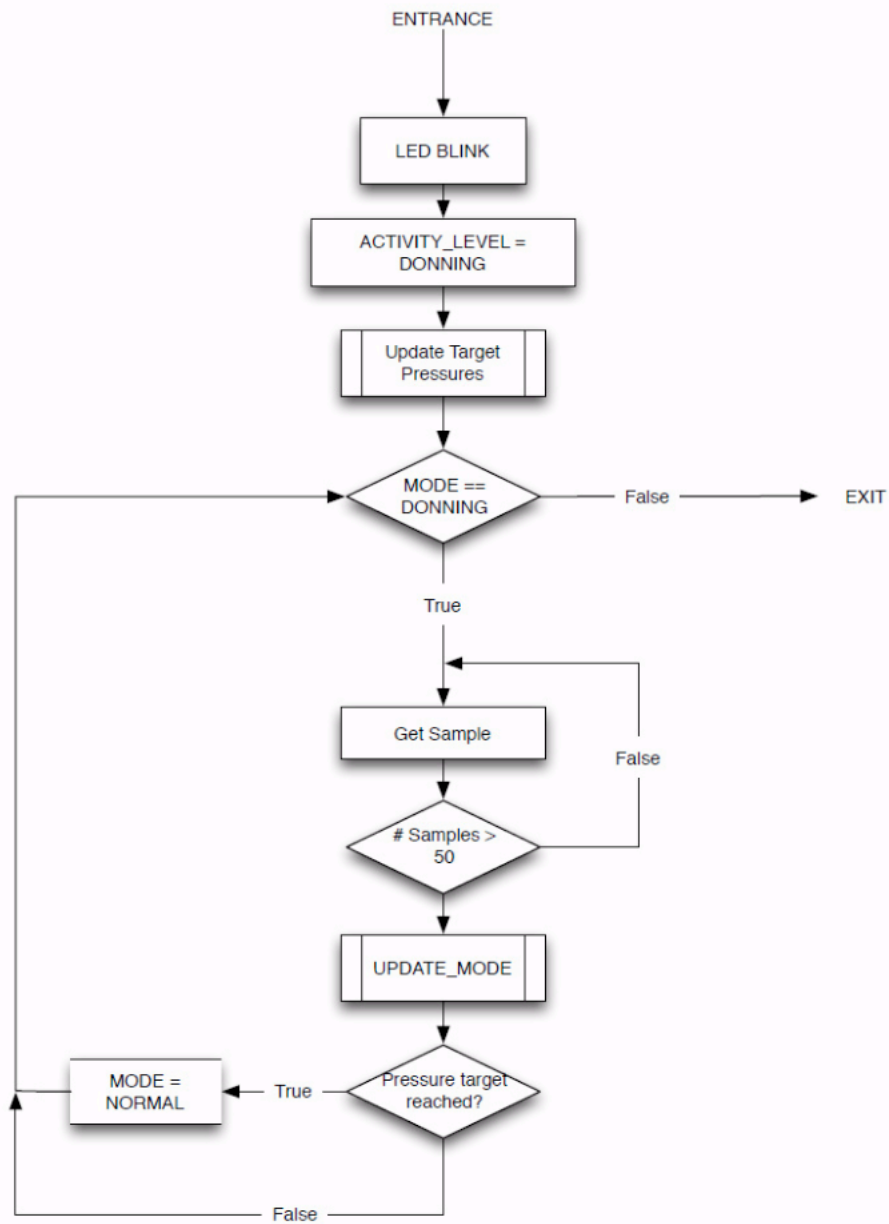
Actual Expenditure: \$326,902

9.

APPENDICES:

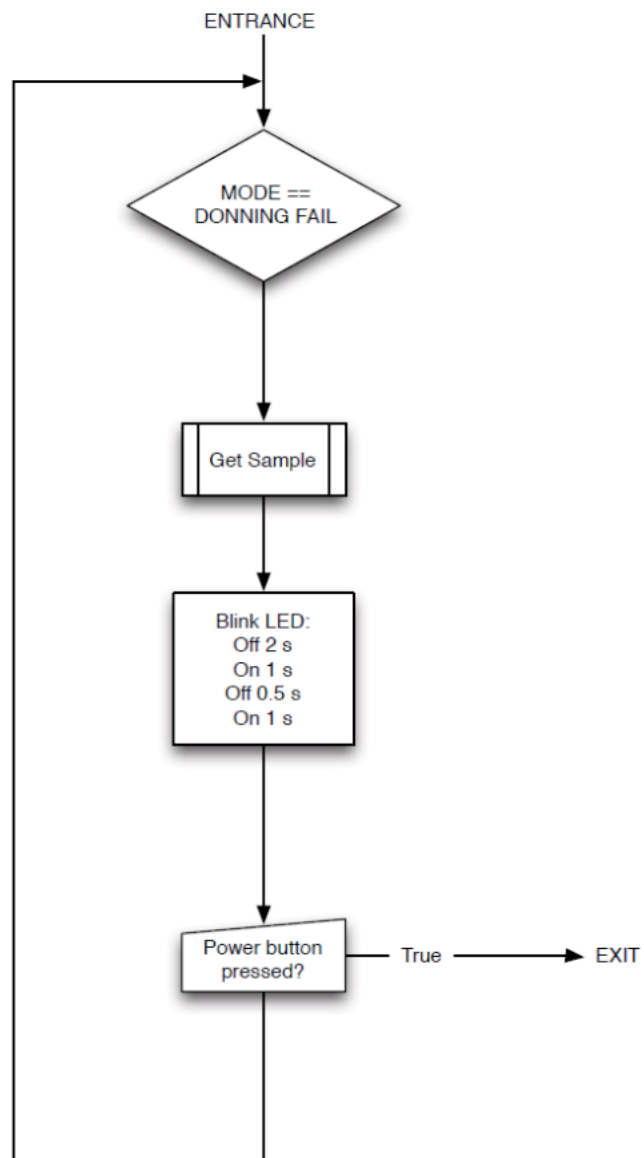
Control Algorithm Flow Chart:

RUN MODE DONNING

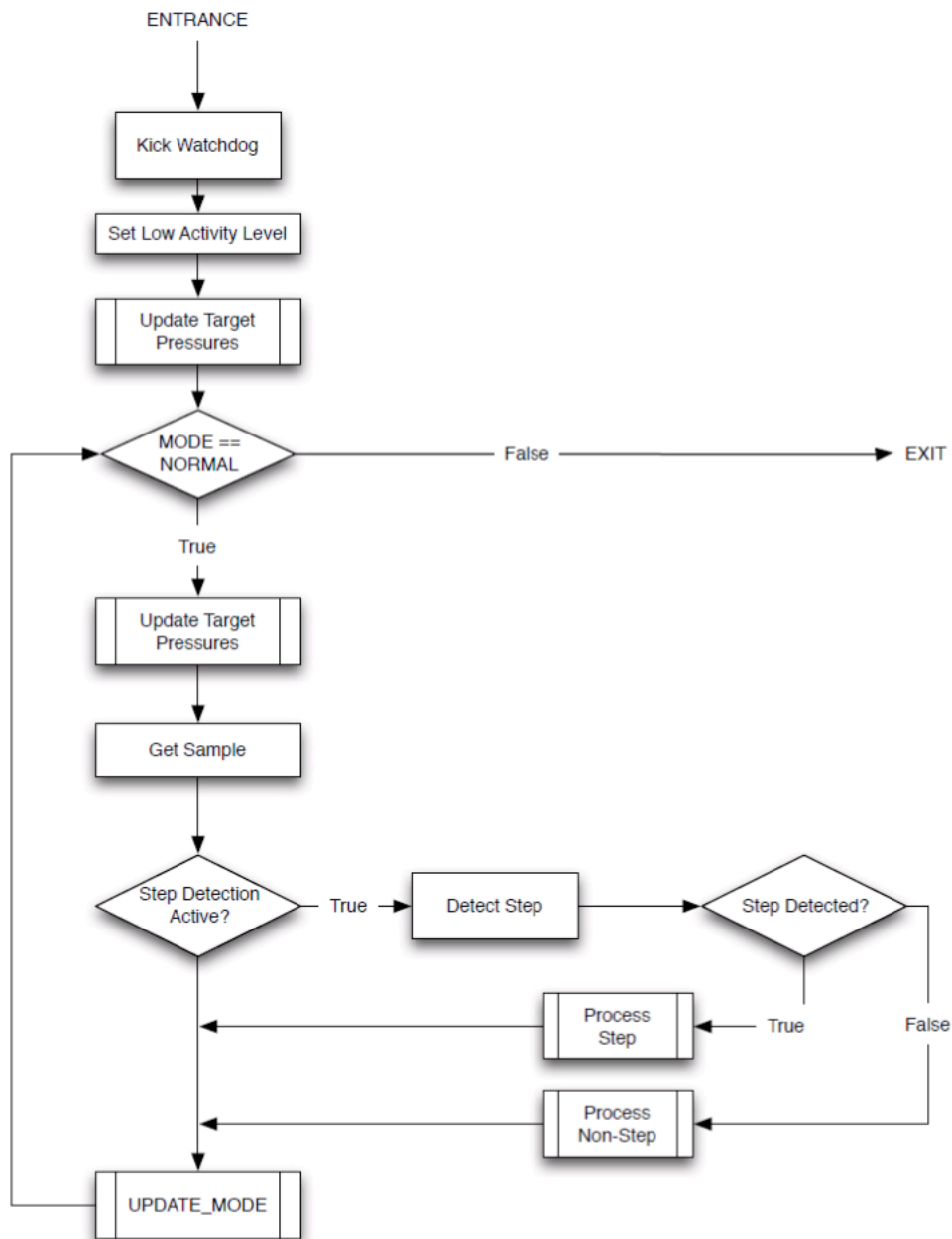


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RUN MODE DONNING FAIL

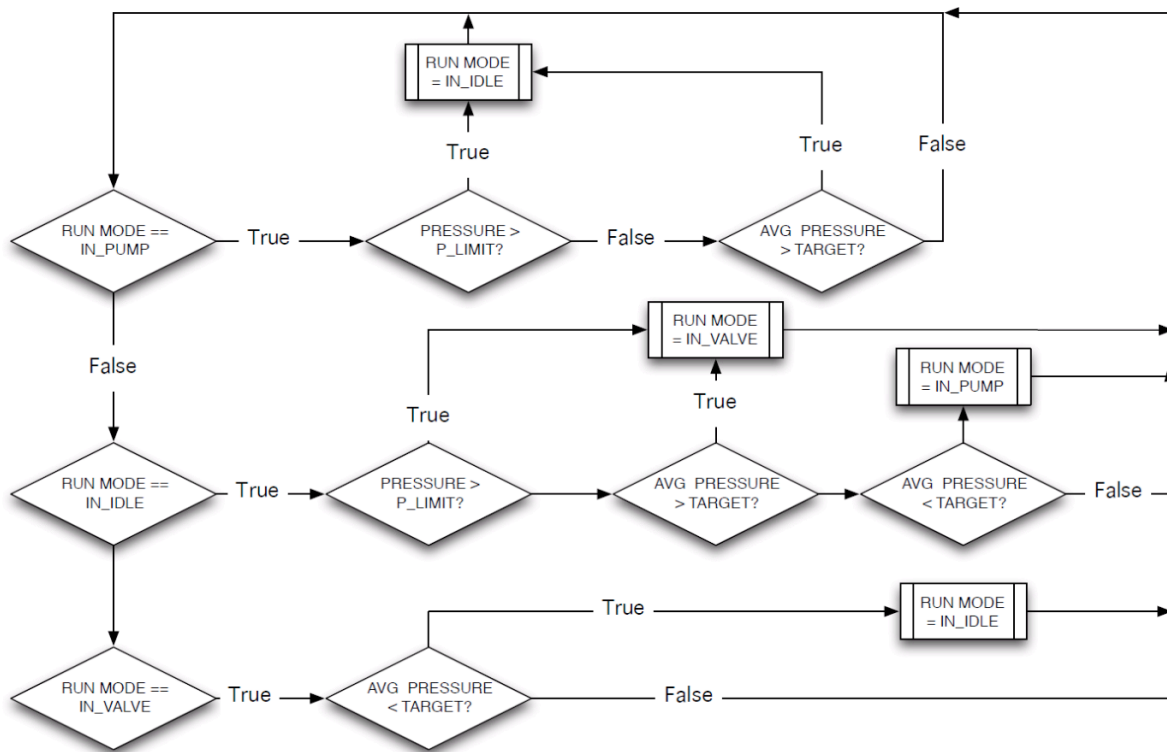


RUN MODE NORMAL

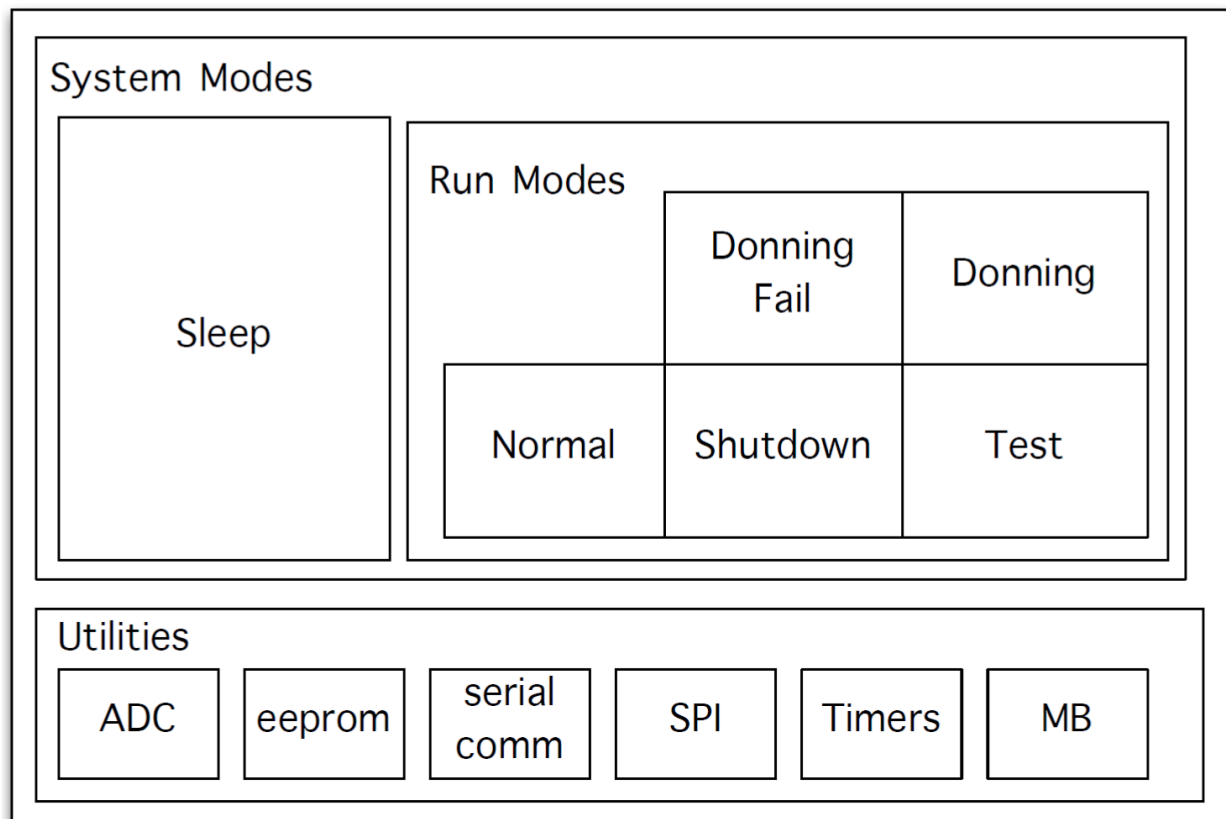


UPDATE MODE

AVG PRESSURE is pressure lowpass filtered
PRESSURE is instantaneous pressure



Firmware Modes and Utilities Chart:



RUN MODE VOLUME CHECK

